AUG - 8 2006

K061500

SICace Dental Implant System

and

SIC Angled Abutments

510(K)
SUMMARY OF SAFETY AND EFFECTIVENESS

DATE: 2006-05-26

Establishment:
SIC invent AG
Birmannsgasse 3
Basel, SWITZERLAND 4055
Registration Number: 3004443656

Owner/Operator:
SIC invent AG
Birmannsgasse 3
Basel, SWITZERLAND 4055
Owner/Operator Number: 9060857

Official Correspondent:
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SIC invent AG
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1. Description of the Device

1.1. Device Name & Classification

	SICace Dental Implant	SIC angled Abutment
Proprietary Device Name:	ENDOSSEOUS IMPLANT, OSSEOINTEGRATED TITANIUM IMPLANT	
Common/Generic Device Name:	ENDOSSEOUS DENTAL IMPLANT, COMPONENTS & ACCESSORIES	
Classification Name:	IMPLANT, ENDOSSEOUS, ROOT-FORM	
Trade Name:	SICace Dental Implant	SIC Angled Abutments
Device Class:	2	
Product Code:	DZE	
Regulation Number:	872.3640	
Medical Specialty:	Dental	

1.2. Description of SICace Dental Implant

SICace dental implant system is a root-form endosseous dental implant device made out of grade 4 titanium according ASTM F 67. The implants are available in three different diameters (ø3.4 mm, ø4.0 mm, ø5.0 mm) and various lengths from 9.5 mm up to 14.5 mm. The anchorage surface is grit blasted and acid etched for faster osseointegration and secondary stability.

Equal to the predicate device SICpro dental implant, the face side of the SICace dental implant has a hexagon drill hole and a standard screw thread to ensure a secure and anti-rotational connection of the congruent abutment and the implant. Throughout the different diameters the hexagon drill hole has identical measurements.

SICace dental implants are delivered single packed in combination with an implant cover screw and supplied in sterile condition (sterilized by gamma-radiation).

1.3. Description of SIC Angled Abutment

SIC angled abutments are various in lengths and diameters and made out of titanium ASTM F 136. Through a hexagon socket and a vertical drill hole, the abutments can be connected with the implant secure and anti-rotational.

SIC angled abutments are supplied in non sterile condition. These parts of the system can be sterilized by the user by using a standardized and validated sterilization process.

2. Predicate Devices

- SIC invent AG, SICpro Dental Implant System, K040757;
- Institut Straumann AG, ITI® synOcta Angled Abutments, K013891
- FRIADENT GmbH, XiVE@ TG Abutment Accessory to the XiVE@ TG Dental Implant Systems, K032302.

3. Indication for Use

The SICace System Dental Implant is a root form endosseous dental implant system that is indicated to be implanted in the upper and/or lower jaw arches. The implants may be used in combination with various SICace System Abutments for single or multiple unit prosthetic attachment to restore a patient's chewing function.

Patient's must be applicable for dental treatment with endosseous implants.

In cases where the ridge is too narrow to receive a 4.0 mm or a 5.0 mm diameter implant, the 3.4 mm implant can be used. Because of reduced strength due to the small diameter, these implants should be rigidly joined to other implants and used only where loads are not extreme.

The SICace System Abutment is intended to be placed into the SICace System Implant to provide a safe and effective fit of screw retained and/or cementable crowns and bridges.

4. Conclusions

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the SICace Dental Implant System, Abutments and Accessories are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2006

Mr. Franz Menean
Managing Director/Senior Consultant
SIC Invent AG
Birmannsgasse 3
Basel,
SWITZERLAND 4055

Re: K061500
Trade/Device Name: SIC®ace Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 28, 2006
Received: June 1, 2006

Dear Mr. Menean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

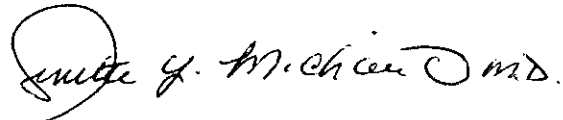
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K061500**

Device Name: **SIC®ace Dental Implant System**

Indications for Use:

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Prescription Use __YES___ AND/OR Over-The-Counter Use __NO_X
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...) Number: K061500